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Pesticide Assessment Guidelines, Subdivision O
Hazard Evaluation: Residue Chemistry
Nature of the Residue: Plants
(Addendum 3 on Data Reporting)

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16. Abstract (Limit: 200 words)
The Data Reporting Guideline (DRG) for Nature of the Residue: Plants, Series 171-4 (a)(1)&(2), gives guidance to pesticide registrants on the format for their study report so that the Agency can review it efficiently. This guidance clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision O, on data reporting. It provides an outline for the study report and describes the topics which should be addressed such as application of radiolabeled materials, identification of residue components, degradation pathways, validation of enforcement methodology, etc. and provides guidance on the presentation of the results of the study. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides.

The DRG for Series 171-4 (a)(1)&(2), Nature of the Residue: Plants is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision O of the Pesticide Assessment Guidelines.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

HAZARD EVALUATION:

RESIDUE CHEMISTRY

Series 171-4 (a)(1)&(2)

Nature of the Residue: Plants

ADDENDUM 3 ON DATA REPORTING

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Subdivision O - Nature of the Residue: Plants

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PESTICIDE ASSESSMENT GUIDELINES

RESIDUE CHEMISTRY

Nature of the Residue: Plants

Subdivision O, Series 171-4

DATA REPORTING

INTRODUCTION

A. Purpose

Plant metabolism studies which provide residue chemistry data on the qualitative nature of the residue are required by 40 CFR 158.125 to support the registration of any pesticide intended for use on a food or feed crop under the amended Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Subdivision O [§§ 171-4(a)(1) and (2)] of the EPA Pesticide Assessment Guidelines provides information to aid the petitioner/registrant in conducting plant metabolism studies. A metabolism study must be submitted for each type of plant for which use is proposed and in general, one metabolism study will be required for each of the crop groups defined in 40 CFR 180.34(f), except for herbs and spices. However, if the results of three metabolism studies on dissimilar crops (e.g., root crop, oilseed and a leafy vegetable) indicate a similar metabolic route in the three crops, then additional plant metabolism studies in other crops for which use is proposed will not be required.

The Data Reporting Guideline is designed to aid the petitioner/registrant in the data/information collection/organization process and thereby facilitate the Agency review process. Data submitters are encouraged to submit complete reports following this guidance for efficient review by the Agency. This guidance pertains to the substance of the data report. PR Notice 86-5, effective on November 1, 1986 (available from the Registration Support and Emergency Response Branch, Office of Pesticide Programs, US EPA) pertains to the physical formating of reports (which are refered to as "studies") and submittal packages. Some of the requirements in PR Notice 86-5 are mandatory.

B. Objective

Plant metabolism studies should characterize the qualitative nature of the total terminal residue and thereby facilitate a chemical definition of the "total toxic residue" in or on the raw agricultural food or feed commodity resulting from application of the pesticide formulated product to crops. These studies are to answer the question, what is the chemical residue?

The term total terminal residue is used to refer to all components of the resultant residue whether or not they are toxic enough to be of concern. Based on the results of the residue characterization studies described in the plant metabolism submission, the petitioner/registrant should propose the chemical definition of the "total toxic residue." The term "total toxic residue" is defined as the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation. All components of the "total toxic residue" must be included in the analysis of the magnitude of the residue for samples used to quantitate the level of residue likely to occur.

If, after exhaustive attempts, the petitioner/registrant is unable to arrive at a determination as to whether the total terminal residue has been sufficiently characterized, which metabolites should be covered by the tolerances, and which components of the residue must be determined by the residue analytical methodology, then these written and documented concerns should be expeditiously communicated to EPA staff in order to arrive at their mutually acceptable and timely resolution prior to the proposed final definition of the "total toxic residue."

RESPONSE TO PUBLIC COMMENTS

The purpose of this section is to acknowledge and address the concerns expressed in the letters of comment received by the Agency in response to the public notice in FEDERAL REGISTER Volume 51, No. 98, pp. 18660-18661, May 21, 1986.

This addendum to the Pesticide Assessment Guidelines [Subdivision O] is to be considered an all-encompassing document. EPA recognizes there are sections in the addendum which do not apply in all cases. Therefore, registrants should exercise scientific judgement in deciding which portions are germane to a specific data submission.

This Data Reporting Guideline (DRG) is not intended to introduce new data requirements or revisions into the Pesticide Assessment Guidelines [Subdivision O] nor is it intended for use by Agency data reviewers as a mere checklist. It is intended to clarify ambiguities in interpretation of those existing Guidelines, and to organize the submission of data to facilitate the review process.

The Residue Chemistry Branch (RCB) has reviewed the nine comments submitted by the registrants and/or committees in regard to the Data Reporting Guideline. All of the comments submitted were study-specific and were addressed as follows:

1. Comment - The appropriateness of the inclusion of the statement regarding the capability of the proposed enforcement analytical method(s) to determine the major components of the terminal residue and all components of the total toxic residue was questioned.

   Response - Under the present guidelines §171-4(a)(1), this statement is required. However, in response to these comments, the statement was modified throughout this DRG and, in addition, a note was made that if the specified statement/information is provided elsewhere within the

overall data submission package, it need not be reiterated in the section on plant metabolism but referenced.

2. Comment - The reporting requirements for dosage rates, quantitation and distribution of total recovered radioactivity, minor metabolites and degradation routes or pathways of metabolism need to be clarified.

   Response - Revisions were made to the DRG in response to those comments whenever possible.

3. Comment - The certification requirement is unnecessary since personnel responsible for conducting the study sign the report and maintain records on the study.

   Response - The requirement is retained in the DRG since it is consistent with the same requirement previously proposed in the DRGs for Magnitude of the Residue: Crop Field Trials and Analytical Method(s).

GUIDELINE

The petitioner/registrant's report on plant metabolism studies should include all information necessary to provide a complete and accurate description of treatments and procedures. The information submitted in the report should include the following elements:

1. Radiolabeling techniques to include rate, method, and time of radiolabel application in relation to the development and growth cycle of the treated raw agricultural commodity (r.a.c.);

2. Extraction, fractionation, and characterization techniques employed for the identification of residue components whether free or bound at each sampling interval;

3. Definition of total terminal residues, to include data for all major components of the total terminal residue reflecting their distribution within the r.a.c. (including processed fractions derived therefrom) expressed as both percentage of the total recovered radioactivity and concentration (parts per million [ppm]) found at time of harvest and/or when utilized for animal feed;

4. A detailed discussion, preferably accompanied by a flowsheet format, of the possible routes of degradation or pathways of metabolism observed in the subject r.a.c.;

5. When enforcement analytical methodology has been developed, these methods must be validated with radiolabeled samples derived from the plant metabolism study, accompanied by a statement made as to their capability to determine the identified major components of the terminal residue whether free or bound/conjugated, and all components of the total toxic residue whether free or bound/conjugated in the r.a.c. [See note under I.B.7.]

The following is the format for the report.

MASTER COVER PAGE

Title page and additional documentation requirements (i.e., requirements for data submission and procedures for claims of confidentiality of data) if relevant to the study reported should precede the content of the study formatted below. These current mandatory requirements are described in PR Notice 86-5.

MASTER TABLE OF CONTENTS AND INDEX

A concise listing, preceding the body of the report, of all essential elements of the study, and the page or table number where the element is located in the report to include the following:

A. Introduction and Summary

B. Materials

C. Methods (Experimental)

D. Results and Discussion

E. Conclusions

F. List of Tables

G. List of Figures (Flowsheets, etc.)

H. References

I. Appendices

I. MASTER INTRODUCTION/SUMMARY

A. General

Overall, this section should include appropriate background and historical information relative to the study. In addition, the purpose and overall summary of the study, a discussion of the results obtained, and conclusions arrived at regarding the qualitative nature of the total terminal residue in the treated crop should also be included in this section.

B. Specific

The following specific topics should be briefly discussed in this section:

1. Registration history and proposed use of the subject chemical.

2. If applicable and/or available via an appropriate citation or reference, compare and contrast observed metabolic routes in the subject r.a.c. to those observed in earlier plant metabolism studies conducted on

the subject r.a.c. or on other commodities or to those observed in animal metabolism studies conducted with the subject chemical.

3. The purpose of the study, to include testing strategies employed and the rationale for the selection of these strategies.

4. The overall experimental procedure employed, to include a discussion, if applicable, of unusual experimental problems encountered, attempts made to alleviate these problems which resulted in deviations from the intended test protocol and the effects, if any, of those deviations on the results of the study.

5. The modes and routes of metabolism observed including a complete description of the identity and quantity (both free and bound) of all major components of the terminal residue and their distribution within the r.a.c. and processed fractions derived therefrom. (The foregoing information could be summarized in a narrative and/or tabular, figure format.)

6. A conclusion concerning the qualitative nature of the terminal residue in the r.a.c. (including processed fractions derived therefrom) at time of harvest or when utilized for animal feed.

7. When enforcement analytical methodology has been developed, these methods must be validated with radiolabeled samples derived from the plant metabolism study, accompanied by a statement made as to their capability to determine the identified major components of the terminal residue, whether free or bound/conjugated and all components of the total toxic residue whether free or bound/conjugated in the r.a.c. The statement should also indicate the detection limits, precision, and accuracy of the methodology employed. [Note: If the specified statement/information is provided elsewhere within the overall data submission package, it need not be reiterated in this section, but referenced as to location in the data submission package.]

II. MATERIALS

A. Test Substance

In this section the following should be included:

1. Identification of the test pesticide active ingredient (ai), including chemical name; common name (ANSI, BSI, ISO); company developmental/experimental name; and Chemical Abstracts Service (CAS) number.

2. Chemical structure(s) for the parent compound and metabolites constituting the residue.

3. Information on relevant formulation parameters as pertinent; e.g., nature of the solvent, carrier, bait, adjuvant, or other matrix in which the radiolabeled pesticide was applied.

4. For radiolabeled test material, report its purity, specific activity in Curies/mole, disintegrations per minute per gram (dpm/g), nature of the radiolabel and its source and the site(s) of labeling in the molecule. The identity of radiolabeled impurities, if any, derived from the test material should also be reported.

5. A rationale provided for selection of radiolabels other than ^{14}C and for site(s) of labeling in the molecule (where possible, emphasis is placed on labeling the ring position).

6. Other - Any and all additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the test chemical, such as physical-chemical properties (e.g., solubility, etc.).

B. Test Site

In this section the following should be included:

1. A detailed description of the overall testing environment utilized for the study (i.e., outdoor test plots, greenhouse, or plant growth chambers) including, as appropriate, a record of environmental conditions experienced during the course of the study (i.e., temperature, rainfall, sunlight) and documentation of soil characteristics at the testing site.

2. An explanation or rationale provided by the petitioner/registrant if the reported testing environment, including testing media, employed in the metabolism study is not representative of or differs significantly from expected cultural practices or environmental conditions under which the test crop would normally be grown.

C. Test Crop

In this section the following should be included:

1. Identification of the test crop including type/variety and crop group classification according to 40 CFR 180.34(f), as revised June 29, 1983; 48 FR 29855;

2. A rationale or statement provided by the petitioner/registrant for selection of a test crop other than that for which use is proposed.

3. Identification of specific crop part(s) harvested and subjected to ^{14}C residue analysis for a determination of the "total terminal residue."

4. The developmental stage(s), general condition (immature/mature, green/ripe, fresh/dry, etc.) and size(s) of the test crop at time of pesticide application(s) and at harvesting(s).

5. Other - Any and all additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the test crop.

III. METHODS

A. Application of the Pesticide

In this section, the following should be included:

1. A detailed description of the type of pesticide application(s) to the test crop (i.e., preplant soil incorporated, over-the-top post-emergent foliar application, bait application, etc.), including the formulation (i.e., solvent, carrier, bait, adjuvant, or other matrix) in which the radiolabeled pesticide was applied and the method of application (i.e., hand sprayer, topical, soil injection, etc.).

2. The actual dosage rate(s) (i.e., mg/kg or ppm of plant or soil treated and expressed as kg ai/ha or lbs ai/acre where possible) used in the study.

3. Number and timing of application(s), between-application interval(s), and treatment to sampling interval(s) (also known as TSI, or PHI).

4. Dates [planting/sowing/transplanting, as applicable; other significant dates in the growing of the crop (e.g., harvesting of immature crop to obtain specific crop part(s) which may be utilized for animal feed); pesticide application(s); harvest of mature crop].

5. An explanation or rationale by the petitioner/registrant for any significant deviation in either the rate or mode of application to the test crop from the intended use pattern.

B. Sample Harvest (Collection)

1. Harvest procedures (method of harvesting or collection [mechanical/hand; from the plant/ground/flotation; etc.]; type of equipment used; number/weight of samples collected per replication and number of replications per treatment level; sample coding/labeling). These procedures should clearly state the sampling procedure used to obtain representative samples.

2. A detailed description of additional relevant information on the growing of the test crop, application(s) of the pesticide formulated product(s), and harvesting(s) of samples.

Refer to the Data Reporting Guideline on Magnitude of the Residue: Crop Field Trials[1] for additional guidance on this subject area.

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[1]Published by NTIS, Document # PB86-248192.

C. Sample Handling and Storage Stability

1. A detailed description of the handling, preshipping storage, and shipping procedures, as applicable, for harvested (collected) samples.

Refer to the Data Reporting Guidelines on Magnitude of the Residue: Crop Field Trials[1] for additional guidance on this subject area.

2. A detailed description of the conditions and length of storage of harvested (collected) samples following their receipt in the laboratory.

Refer to the Data Reporting Guidelines on Storage Stability Study[2] for additional guidance on this subject area.

D. Analyses of Radioactive Residues

1. Quantitation and distribution of total recovered radioactivity

a. Total recovered (i.e., combustible) radioactivity remaining on the plant at time of sampling or harvest should be reported.

b. Quantitative radioactivity data reported for all plant parts sampled, including fractions thereof which may be processed into food or feed, at time of normal harvest or at a stage of development when normally utilized for animal feed.

c. A detailed description of sample preparation (i.e., dissection, grinding, lyophilization, etc.) prior to oxidative combustion/ liquid scintillation analyses.

d. A quantitative accountability for a majority of total radioactivity recovered from the treated crop at times of sampling or harvest as a result of aggregate sample analyses performed above in item (1)(c).

e. A detailed description provided in narrative, figure, or tabular format of total distribution of radioactivity in the treated crop (and processed fractions derived therefrom) at time of sampling or harvest.

f. Details of analytical method parameters including descriptions of equipment used for determining total radioactivity in each sample should be furnished.

g. Details of radioactive counting data for selected representative samples to include counting times, total counts recorded, corrected counts, counting efficiencies, other raw data (sample

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[1,2]Published by NTIS, Document # PB86-248192.

sizes, ppm equivalents found, sensitivity, limit of detection) including representative calculations should be reported.

h. For each sample analyzed (plant part or fraction) results should be reported as: (1) total radioactive counts (dpm/ug); (2) the percentage that these radioactive counts represent of the total recovered radioactivity in the treated plant at time of sampling or harvest; and (3) the ppm equivalents (expressed as parent compound) that these radioactive counts represent of the total recovered radioactivity in the treated plant at time of sampling or harvest.

2. Extraction and Fractionation of Radioactivity

a. A complete description, preferably accompanied by a flowsheet or diagram depicting the overall extraction and fractionation strategies (schema) employed for each sample matrix analyzed.

b. A discussion of and rationale for the selection and extraction sequence for extracting solvent (polar vs nonpolar) used and extraction procedures (i.e., blending, maceration, partitioning, soxhlet) employed, including use of additional techniques (i.e., decomplexing reagents, ultrasonics, etc.) should be provided.

c. A description of conditions employed for the acidic, basic and/or enzymatic hydrolysis of (the filter cake or residue remaining from) previously extracted plant tissue and/or water soluble plant extracts to release conjugated residues from these samples. Specific information on the source, purity, specificity, and activity of all enzymatic preparations utilized for hydrolysis should also be provided.

d. Calculations provided showing the ratio and/or amounts of total free vs conjugated parent compound and/or metabolites in each extracted sample matrix.

e. The petitioner/registrant should provide a quantitative estimate of residual radioactivity (i.e., "unextractable or bound") remaining in the extracted sample matrix following both exhaustive solvent extractions and hydrolytic treatments. The residual radioactivity reported should be expressed as both percentage and ppm (as parent equivalents) of total recovered radioactivity. Attempts at "bound residue" extraction by exotic or other procedures, or extractions following repeated treatments with concentrated acids and/or bases at elevated temperatures should also be reported by the petitioner/registrant and a rationale for their use given.

f. Radiochemical extraction efficiencies calculated and reported for all harvested plant tissues.

g. The efficiency of separation and purification for all fractionation and isolation techniques employed in the study (i.e., solvent partitioning, high voltage electrophoresis, ion-exchange, or exclusion column chromatography, HPLC using gradient elution, 2-dimensional thin-layer radioautography employing multiple solvent systems) should be reported for a representative sample.

h. Data to account for or track loss of radioactivity in each subsequent step of the fractionation and isolation procedure should be provided and attempts made by the petitioner/registrant to minimize these losses should be discussed.

i. The petitioner/registrant should report detailed procedures for the fractionation of "unextractable or bound" radioactivity in plant tissues into proteins, starch, lignin, cellulose, etc., only if these residues, as reported in item (2)(e) above, are located in edible plant parts used for food or animal feed and their total concentration is generally greater than 10 percent of the total radioactivity recovered from the treated plant or when normalized to use-conditions generally greater than 0.1 ppm (expressed as parent equivalents).

j. Following chemical analyses of the fractionated plant tissues described above in item (2)(i) for amino acids, glucose, etc., the petitioner/registrant should then report if significant quantities of the original radioactive residue characterized as "unextractable or bound" have been incorporated into these natural products.

k. The amount of radioactivity in each sample fraction (e.g., water soluble, organosoluble, released by hydrolysis, etc.) should be quantified and reported in terms of total radioactive counts, and as both percentage and ppm (as parent equivalents) of total radioactivity recovered in the original sample matrix analyzed.

3. Characterization of Radioactivity

a. A complete tabular listing and description of all known and suspected metabolites of the parent compound (model compounds, including their structure and purity) used to facilitate the characterization and/or identification of unknown sample metabolites should be provided.

b. Calculations should be provided and data reported for both sample and reference R_f values on TLC radioautograms and for relative retention times on GC and HPLC columns. Unexpected deviations or variances of observed from expected values including loss of sample resolution between analytes in subsequent chromatographic analyses should be reported and steps taken to correct these problems should be discussed.

c. The petitioner/registrant should also provide complete details of additional confirmatory analytical procedures used to separate and characterize metabolites [i.e., high voltage electrophoresis, ion-exchange, or exclusion chromatography, derivatization, etc.] and determinative methods (i.e., Mass Spectroscopy in EI and CI modes) used for ultimate identification of metabolite(s).

d. All lost or unaccounted for radioactivity in each plant extract or fraction should be explained as fully as possible and the amount reported should be expressed as both percentage and ppm (as parent equivalents) of total radioactivity recovered from the particular plant part or fraction analyzed and of the total plant at harvest (terminal residue) or when utilized as an animal feed.

e. Individual and/or aggregate quantitative radioactive residue data provided for all non-identified and/or non-characterized discrete extractable and resolvable radioactive entities with amounts reported as in item 3(d) above.

f. The petitioner/registrant should report each of the major metabolite components (i.e., those generally comprising $\geq$ 10 percent of the total recovered radioactive residue) and, if possible, provide information on the chemical nature of discrete (minor) metabolite components. Major metabolite components should be quantified with amounts reported as in item 3(d) above; quantification of minor metabolite components should be attempted and the results reported, if possible.

g. The petitioner/registrant should report data/information delineating attempts made to chemically characterize conjugated or complex bound chemical species originating from the parent pesticide only if significant quantities of these "unextractable or bound" residues are present in edible plant parts used for food or animal feed (see testing criteria described in item (2)(i) above) and if the results of the fractionation/characterization study described above in item (2)(j) also indicated that significant levels of incorporation of these residues into natural plant products (i.e., amino acids, glucose, lignin, etc.) did not occur.

h. Quantitative data (with amounts reported as in item 3(d) above) should also be reported by the petitioner/registrant for each minor metabolite component identified in item (3)(f) above if this minor metabolite is also identified as a discrete extractable and identifiable component of the bound residues chemically characterized in item (3)(g) above and its total concentration (free and bound) generally comprised $\geq$ 10 percent of the total recovered radioactive residue.

i. When enforcement analytical methodology has been developed, the petitioner/registrant must report the results of analysis by these methods on radiolabeled samples derived from the plant metabolism study. The analysis should specify what percentages of the total radioactivity and of each labeled and identified major component of the terminal residue whether free or bound/conjugated in/on the treated crop at time of sampling or harvest are accounted for by these methods. [See note under I.B.7.]

j. A complete description of all instrumentation, equipment, and reagents used, including operating conditions of the instrumentation utilized for the separation, characterization, and identification of radioactive residues should be submitted. Photographs of radio TLC plates as well as samples or reproductions of HPLC/GLC chromatograms including mass spectral scans, etc., should also be submitted.

E. Other - Any and all additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the conduct of the plant metabolism study and the determination of the total terminal residue.

IV. RESULTS AND DISCUSSION

A. Test Strategies

This should include a discussion of deviations made from the intended testing protocols or strategies as a result of unusual experimental problems or conditions encountered in growing, treating, or sampling the test crop to include difficulties in extraction, fractionation, and characterization of residues and, if applicable, specific extraction and characterization strategies employed for unextractable or bound residues; including a discussion of the impact or effects, if any, of those deviations on the results of the study.

B. Metabolic Pathways

If possible, a detailed discussion, preferably accompanied by a flowsheet format, of the routes of degradation or pathways of metabolism observed in the subject r.a.c. should be provided. For discussion purposes, the observed metabolic routes in the subject r.a.c. may be compared and contrasted to known and previously reported metabolic pathways in other r.a.c.s or observed in animal metabolism studies conducted with the subject chemical.

C. Characterization and Distribution of Total Terminal Residue

1. In a tabular or graphic format, identification [including name, structure, and quantity (expressed both as percentage and ppm as parent equivalents)] of all major components of terminal residue in r.a.c. (both free and conjugated/bound) and their distribution

within the r.a.c. including plant parts and processed fractions derived therefrom.

2. If the immature r.a.c.(including plant parts and processed fractions thereof) is normally utilized for animal feed, then identification and quantification of all major components of the residue present at that stage of plant development must also be reported as in item (C)(1) above.

3. Provide information on any properties and/or characteristics of, their quantities, and distribution within the r.a.c. of all significant unidentifiable and/or uncharacterizable components of the terminal residue.

4. When enforcement analytical methodology has been developed, the petitioner/registrant must report the results of analysis by these methods on radiolabeled samples derived from the plant metabolism study. The analysis should specify what percentages of the total recovered radioactivity and of each labeled and identified major component of the terminal residue whether free or bound/conjugated in/on the treated crop at time of sampling or harvest are accounted for by these methods. [See note under I.B.7.]

D. Residue Analytical Methodology

This should include a discussion of the efficiency of extraction procedures employed for all harvested plant tissues and quality assurance measures/precautions taken to ensure the integrity of all stored samples prior to analysis. When enforcement analytical methodology has been developed, these methods must be validated with radiolabeled samples derived from the plant metabolism study accompanied by a statement made by the registrant/petitioner as to the capability of these methods to determine the identified major components of the terminal residue whether free or bound/conjugated and all components of the total toxic residue whether free or bound/conjugated in the r.a.c. [See note under I.B.7.]

E. Statistical Treatment(s)

If during the course of the plant metabolism study, statistical tests are applied to the raw data obtained during sampling/analyses, then representative examples of these tests should be described.

F. Other - Any and all additional information the petitioner/registrant considers appropriate and relevant to provide a complete and thorough description of the plant metabolism study including quality control measures/precautions taken to ensure validity of all aspects of the study.

V. CONCLUSIONS

Discuss conclusions that may be arrived at as a result of the submitted plant metabolism study, such as:

A. The routes or pathways, mechanisms involved and extent or degree of metabolism observed when the subject r.a.c. is grown to maturity or harvest.

B. The nature, amount, and distribution of the total terminal residue in the r.a.c. (including processed fractions derived therefrom at time of harvest or when normally utilized for animal feed) resulting from the proposed use of the pesticide.

C. Based on the results of validation studies conducted on radiolabeled plant samples, the capability of developed and available enforcement analytical methodology to determine the identified components of the terminal residue whether free or bound/conjugated, and the capability of the same or modified analytical methodology to determine all components of the total toxic residue whether free or bound/conjugated in the r.a.c. [See note under I.B.7.]

VI. TABLES/FIGURES

A. Tables [examples given are]:

1. Tables of weather and/or environmental data.

2. Distribution and quantity of radioactivity in various harvested plant parts.

3. Name, structure, purity, for all (model compounds) metabolites utilized in study.

4. HPLC/GLC retention times and TLC R_f values for parent compound, metabolites, related compounds and model compounds under different column, solvent (elution) conditions.

5. Name, structure, quantity and location in r.a.c. of all major identified components of terminal residue.

6. Properties, characteristics, quantities and distribution within r.a.c. of all significant unidentified components of the terminal residue.

B. Figures [examples given are]:

1. Discussion or diagram of location, topography, and size of outdoor test plot(s).

2. Photographs, figures, or diagram of greenhouse and/or plant growth chamber facilities used in study.

3. Overall extraction and fractionation strategies or schema employed for each sample matrix analyzed.

4. Distribution of radioactivity in various ion exchange (exclusion) or preparative HPLC/GLC fractions.

5. Metabolism flow diagrams or charts.

VII. CERTIFICATION

A signed and dated certification of authenticity by, and identifying information (typed name, title, affiliation, address, telephone number) on, the personnel responsible for the various phases of this report (e.g., Study Director, Field Supervisor, and Laboratory Supervisor).

VIII. REFERENCES

IX. APPENDIX(ES)

A. Representative chromatograms, spectra, etc. [as applicable].

B. Cite or reference reprints of published and unpublished literature, company reports, letters, analytical methodology, etc., used by the petitioner/registrant [unless physically located elsewhere in the overall data report, in which case cross-referencing will suffice].

C. Other - Any relevant material not fitting in any of the other sections of this report.